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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,637	12/30/2003	Nancy L. Brackett	7230-9	6890
7590	06/13/2006		EXAMINER	
Stanley A. Kim, Ph.D., Esq. Akerman Senterfitt Suite 400 222 Lakeview Avenue West Palm Beach, FL 33401-6183			SCHUBERG, LAURA J	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 06/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/748,637	BRACKETT ET AL.	
	Examiner Laura Schuberg	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) 4 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09/14/2004.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

## DETAILED ACTION

### ***Claim Objections***

Claim 4 is objected to because of the following informalities: The phrase "spinal cord injury" should be written out next to (SCI) for clarity purposes. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexander et al (US 6,180,355 B1).

Claims 1, 2, 5, 6, 8-19 are drawn to a method of increasing motility of sperm by providing from a subject a biological sample comprising sperm and at least one cytokine and contacting the biological sample with an agent that inactivates or reduces the biological activity of the at least one cytokine selected from the group consisting of TNF $\alpha$ , IL1 $\beta$ , and IL6.

Alexander teaches method of treating patients who suffer from chronic pelvic pain syndrome (CPPS) (column 1). Since CPPS has adverse effects upon sexual function (column 1 line 33) it also impairs fertility. Alexander teaches that CPPS is

associated with elevated levels of cytokines TNF $\alpha$ , IL1 $\beta$ , and IL6 (column 5 line 61) and the method of treatment consists of administering a therapeutically effective amount of an anti-cytokine compound or composition (column 5 line 15) (claims 1,2). The term "anti-cytokine" is defined to include compounds which inhibit production, processing or activity of a cytokine or its receptor (column 8 line 1). Alexander teaches that the method also provides a method for treating men determined to be suffering from a disorder associated with elevated levels of one or more cytokines in one or more components or fractions of semen comprising administering one or more ant-cytokine agents (column 7 line 35) (claims 5,6). Alexander teaches that compounds that interfere with the production and/or activity of various cytokines are widely known and that such compounds may bind to the cytokine or its receptor, thereby preventing the natural cytokine-receptor interaction (column 7-8). The use of antibodies that specifically bind to the cytokines such as TNF $\alpha$  , IL1 $\beta$ , and IL6 is taught (column 11 line 10) (claims 8-15) as well as the use of soluble cytokine receptors that bind to the cytokines TNF $\alpha$ , IL1 $\beta$ , and IL6 (column 29, US 5,770,401) (claims 16-19).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 and 8-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al (US6,180,355 B1) in view of Basu et al (Journal of Andrology 2002).

Claims 1, 2, 5, 6, 8-19 are drawn to the method as described above.

Claim 3 is drawn to the method of claim 2 wherein the condition that impairs fertility is leukocytospermia.

Claim 4 is drawn to the method f claim 1 wherein the subject has SCI (spinal cord injury).

Alexander teaches the method of claims 1, 2, 5, 6, 8-19 as described above, but does not teach wherein the subject has leukocytospermia or an SCI. However, Alexander does teach that the method may be used to treat conditions associated with elevated levels of a cytokine, such as TNF $\alpha$  (column 5 line 12) and that there is a connection between leukospermia and levels of IL-6 (references cited, Shimoya et al).

Basu teaches that there is a relationship between leukocytospermia and decreased sperm motility in the semen of men with SCI (abstract). Basu also teaches that it is reasonable to assume that most of the abnormal levels of cytokines in the

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semen can be attributed to the abnormal levels of cytokine-producing cells (leukocytes) found in these patients and that they have a detrimental effect on sperm motility (p.555).

One of ordinary skill in the art would have been motivated to use the method of Alexander to treat men with SCI and leukocytospermia because Alexander teaches that the method can be used to treat conditions associated with elevated levels of a cytokine (column 5 line 12) and Basu teaches that men with SCI and leukocytospermia have elevated levels of cytokines (p.555). One of ordinary skill in the art would have had a reasonable expectation of success because Alexander teaches the use of ant-cytokine compounds for IL-6 and also that there is a connection between IL-6 and leukospermia (also known as leukocytospermia).

Claims 1, 2, 5-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al (US 6,180,355 B1) in view of Faber et al (Obstetrics and Gynecology 2001) and Slesarev (US 5,834,435).

Claims 1, 2, 5, 6 and 8-19 are drawn to the method as described above.

Claim 7 is drawn to the method of claim 1 wherein the biological sample comprises a fluid produced by the female reproductive tract.

Alexander teaches the method of claims 1, 2, 5, 6, 8-19 as described above, but does not include wherein the biological sample comprises a fluid produced by the female reproductive tract. However, Alexander does teach that the method may be used to treat conditions associated with elevated levels of a cytokine, such as TNF $\alpha$  (column 5 line 12).

Faber teaches that peritoneal fluid from patients with endometriosis has been shown to have elevated levels of IL1 $\beta$ , TNF $\alpha$ , and IL-6 and that this fluid has a deleterious effect on sperm motility and fertility (p.668 column 2).

Slesarev teaches a method of treating elevated levels of TNF $\alpha$  by vaginal application of a compound that inhibits TNF $\alpha$  (column 6 line 20).

One of ordinary skill in the art would have been motivated to use the method of Alexander to treat endometriosis in women because Faber teaches that peritoneal fluid from patients with endometriosis has been shown to have elevated levels of IL1 $\beta$ , TNF $\alpha$ , and IL-6 (p.668) and Alexander teaches that the method may be used to treat conditions associated with elevated levels of a cytokine, such as TNF $\alpha$  (column 5 line 12). This treatment would have required that the biological sample being treated would have included fluid produced from the reproductive tract (peritoneal fluid). One of ordinary skill in the art would have had a reasonable expectation of success because Slesarev had previously administered vaginally a compound that inhibits TNF $\alpha$  (column 6 line 20).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Schuberg

SANDRA E. SAUCIER  
PRIMARY EXAMINER

